UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

# FSIS NOTICE	47-02	11/20/02

FSIS Actions Concerning Suppliers that may be Associated with *Escherichia coli (E. coli)* O157:H7 Positive Raw Ground Beef Product

I. What kind of notice do program personnel provide before collecting raw ground beef samples for *E. coli* O157:H7 testing?

A. At federally inspected establishments (excluding import establishments):

1. Before collecting routine samples of raw ground beef for *E. coli* O157:H7 testing, inspection program personnel notify official establishment management and provide enough time for the establishment to hold the entire sampled lot.

2. Inspection program personnel inform the establishment of the reason they are taking the sample (e.g., routine monitoring, follow-up sampling in response to an *E. coli* O157:H7 positive, a traceback sample, or follow-up sampling in response to an *E. coli* O157:H7 outbreak).

B. At retail facilities:

1. Compliance Officers are to make an effort to notify the retail facility the day before they plan to collect the sample so the retail facility can prepare to hold the expected sampled lot. However, in cases when this is not possible, Compliance Officers should try to get to the retail facility as close to the beginning of the grinding operation as possible. Compliance Officers do not collect product from retail cases.

2. At this time, Compliance Officers obtain from the retail facility the names and establishment numbers of the establishments supplying the source materials for the lot of ground beef being sampled. In the event the source material utilized is store generated trim, the Compliance Officer obtains and records the names and establishment numbers of the establishments from which the store generated trim was derived. This information is recorded on the retail worksheet. In addition, the Compliance Officer records the supplier lot number, production date, and other identifying information that would be useful to the supplier if it is later notified of an *E. coli* O157:H7 positive. This information is posted to the OUTLOOK folder established for this purpose.

B. At import establishments:

Import inspectors notify the import establishment when a shipment is to be sampled for *E. coli* O157:H7 so that the establishment has an opportunity to voluntarily hold the product until the results are reported. FSIS holds the product to be sampled when intensified sampling for *E. coli* O157:H7 is being performed.

II. What happens if there is a presumptive positive at a Federal grinding establishment?

The Inspector in Charge (IIC) uses Laboratory Electronic Application Results Notification (LEARN) to check for sample results. If the results are presumptive positive, the IIC notifies establishment management that the sample was presumptive positive. The IIC also informs the establishment that if the results are confirmed positive, he or she will be collecting (under the authority of 9 CFR 320.1) the following information regarding the suppliers of the presumptive positive product:

1. Name of establishment, Point of Contact,, and Phone number
2. Supplier lot number
3. Production date

The IIC advises the establishment that it should begin to gather the information above.

Note: On weekends and holidays, if the establishment is not operating, the District Office carries out the above process.

III. What will FSIS do if the sample is confirmed positive for *E. coli* O157:H7?

A. At federally inspected establishments (excluding import establishments):

1. The IIC collects from the establishment the information in paragraph II above. The IIC makes note of any information that the establishment is unable to provide.

2. The IIC forwards the information, via email, to the designated District Office contact for this procedure, with a "cc" to the Circuit Supervisor.

3. The District Office contact person notifies all of the supplying establishments in his or her own District, by telephone, of the positive finding and provides the suppliers the production date for the product that the supplier provided to the grinder, the lot number of the supplied product, and other information that would be useful to the supplier to help identify the *E. coli* O157:H7 positive lot.

4. District contact persons document the date and time of the oral notification and send this information along with the supplier information to the Director, Recall Management Division, via electronic mail.

5. If any of the suppliers are located in other Districts, the District Office contact provides the supplier information to his or her counterparts in the appropriate Districts so that notification to the suppliers is carried out by the District Office within which the supplier is

located.

6. The Recall Management Division issues a written notification to each supplier, with a "cc" to the applicable District Office.

NOTE: If the confirmed positive sample includes imported product, then the District Office contact person provides the supplier information to the Office of International Affairs (OIA) contact person. The OIA contact person in turn forwards this information to the head of the inspection service in the country where the supplier establishment is located.

B. At retail facilities:

1. The District Office is notified of a retail positive through the Biological Information Transfer and E-mail System (BITES).

2. The District Office contact accesses the OUTLOOK folder with the list of suppliers for the sampled product that tested positive.

3. The District Office contact person notifies all of the supplying establishments in his or her own District, by telephone, of the positive finding and provides the suppliers the production date for the product the supplier provided to the grinder, the lot number of the supplied product, and other information that would be useful to the supplier to help identify the *E. coli* O157:H7 positive lot.

4. District contact persons document the date and time of the oral notification and send this information along with the supplier information to the Director, Recall Management Division, via electronic mail.

5. If any of the suppliers are located in other Districts, the District Office contact provides the supplier information to his or her counterparts in the appropriate Districts so that notification to the suppliers is carried out by the District Office within which the supplier is located.

6. The Recall Management Division issues a written notification to each supplier, with a "cc" to the applicable District Office.

NOTE: If the confirmed positive sample includes imported product, then the District Office contact person provides the supplier information to the OIA contact person. The OIA contact person in turn forwards this information to the head of the inspection service in the country where the supplier establishment is located.

C. At the supplying establishment:

1. The District Office informs the Circuit Supervisor and IIC of each supplier establishment notified. This notification includes identifying information about the production lot that the establishment supplied. **It is important to note that this notification is to ensure that the establishment knows that it could be the source of the *E. coli* O157:H7. It is not a definitive determination that the supplier establishment is the actual source of the pathogen.**

2. The IICs at the supplying establishments ensure that inspection program personnel perform a HACCP 02 procedure to verify that the establishment met all regulatory

requirements at all CCPs in the HACCP plan (monitoring, verification, recordkeeping, corrective actions, and reassessment) for the production lots sent to the establishment at which the positive was found. If inspection program personnel find noncompliance, they take appropriate action as described in FSIS Directive 5000.1.

D. At import establishments:

1. If the product is on hold at the import establishment, whether on FSIS hold or voluntary hold, the IIC refuses entry of the lot.

2. If the lot has moved into commerce from the import establishment:

a. The IIC sends, via e-mail, to the designated District Office contact for this procedure, the country of origin, foreign country establishment number, health certificate number, shipping mark, and the name and address of the consignee from the health certificate. Additionally, if the Importer of Record from block 6a of FSIS Form 9540-1, Import Inspection Application and Report, is different from the Consignee on the health certificate, the IIC provides this information.

b. A "cc" is sent to the Circuit Supervisor.

c. The IIC faxes a copy of the health certificate, FSIS Form 9540-1, and FSIS Form 10,210-3, Requested Sample Programs Form, to the TSC at (402) 221-7479.

d. The District Office contact person notifies the Consignee or the Importer of Record in his or her own District by telephone of the positive finding, and provides the country of origin, foreign country establishment number, health certificate number, and the shipping mark.

e. The TSC faxes the information to the OIA, which in turn notifies the head of the inspection service in the foreign country of the positive sample and requests that appropriate action be taken.

f. If the Consignee or Importer of Record is located in another District, the District Office contact provides the information to his or her counterpart in the appropriate District so that notification can be carried out by the District Office within which the Consignee or Importer of Record is located.

g. The District Office contact person documents the time and date of the verbal notification and sends this information along with the information to the Director, Recall Management Division, via electronic mail.

h. The Recall Management Division issues written notification to the Consignee or Importer of Record.

IV. What FSIS office maintains the supplier information collected?

The Office of Field Operations will develop and maintain a database of the information gathered regarding suppliers. The information will be kept in an Outlook folder.

Philip S. Derfler /s/

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